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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,563	06/05/2007	Zoser B. Salama	7014-230	7255

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JOYCE VON NATZMER
PEQUIGNOT + MYERS LLC
200 Madison Avenue
Suite 1901
New York, NY 10016

EXAMINER	
HABTE, KAHSAY	
ART UNIT	**PAPER NUMBER**
1624	

MAIL DATE	DELIVERY MODE
11/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,563	SALAMA, ZOSER B.	
	Examiner	Art Unit	
	Kahsay Habte	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/5/07&12/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-15 are pending in this application.

Election/Restriction

2. Applicant's election with traverse of Group II (R1 and R2 together with the N atom to which they are attached form a morpholino ring) on 10/15/2007 is acknowledged. The traversal is on the ground that "the PCT state that the inclusion of more than one invention in one international application is permitted if all inventions are so linked as to form a single general inventive concept (Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features". This is not found persuasive because the United Sates Patent and Trademark Office is *not* bound by the lack of unity determination by another International Searching Authority. MPEP 1875 states that whether or not the question of unity of invention has been raised by the International Searching Authority, it may be considered by the examiner when serving as an authorized officer of the International Preliminary Examining Authority. Thus, the Examiner is *not* bound by any previous determination made. In addition, 37 C.F.R. 1.484 indicates that the international preliminary examination is a non-binding opinion. Finally, 37 C.F.R. 1.499 states that, if the Examiner finds that a national stage application lacks unity of invention under 37 C.F.R. 1.475, the Examiner may in an Office action require the applicant in the response to that action to elect the invention to

which the claims shall be restricted. Thus, the determination of lack of unity is proper under the PCT treaty.

The requirement is still deemed proper and is therefore made FINAL.

3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action.

Information Disclosure Statement

4. Applicant's Information Disclosure Statement, filed on 06/05/2007 and 12/26/2006 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Note that the IDS submitted 06/05/2007 contain NPL reference that are databases from Beilstein and Caplus online (1-3 and 6-10) with no date and has not been considered. At least a year in which these references are available as a prior art should be provided in the 1449.

In regard to the IDS submitted on 10/26/2006, most of the references (Russian) submitted on page 2 of the IDS have not considered. Applicants have to submit the missing references.

Claim Rejections - 35 USC § 102

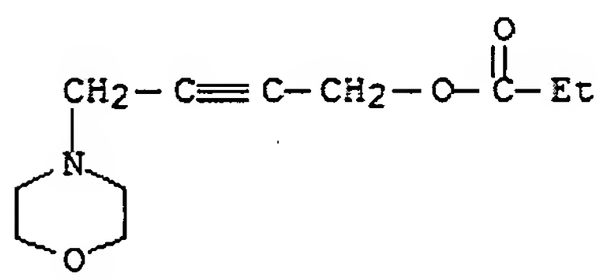
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

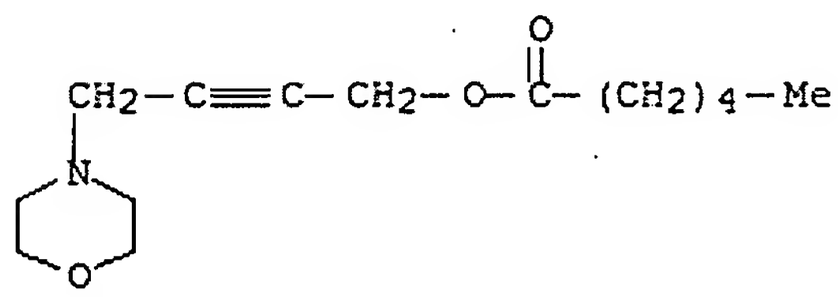
Claims 1-6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ergashev et al. Izvestiya Vysshikh Uchebnyk Zavedenii, Khimiya I Khimicheskaya Tekhnologiya (1986), 29(1), 39-41. Cited reference teaches the following compounds that are the same as applicants. Applicants have cited this reference in the 1449.

RL: SPN (Synthetic preparation); PREP (Preparation)
(preparation of)

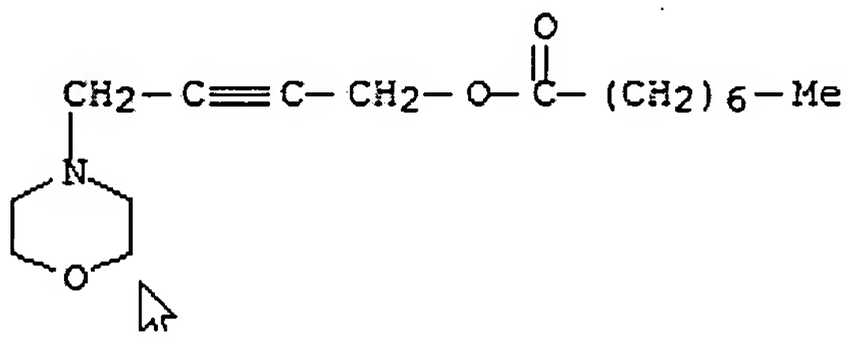
RN 106087-86-9 CAPLUS
CN 2-Butyn-1-ol, 4-(4-morpholinyl)-, propanoate (ester) (9CI) (CA INDEX NAME)



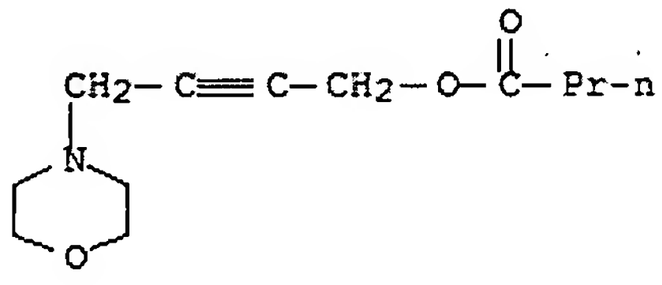
RN 106087-89-2 CAPLUS
CN Hexanoic acid, 4-(4-morpholinyl)-2-butynyl ester (9CI) (CA INDEX NAME)



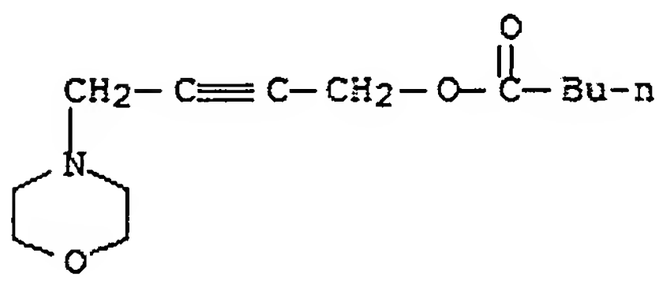
RN 106087-90-5 CAPLUS
CN Octanoic acid, 4-(4-morpholinyl)-2-butynyl ester (9CI) (CA INDEX NAME)



RN 106087-87-0 CAPLUS
CN Butanoic acid, 4-(4-morpholinyl)-2-butynyl ester (9CI) (CA INDEX NAME)

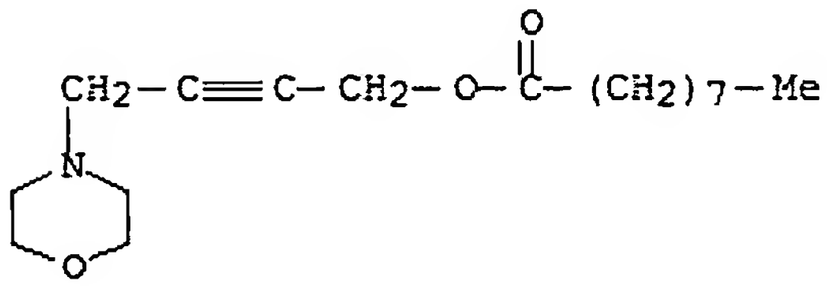


RN 106087-88-1 CAPLUS
CN Pentanoic acid, 4-(4-morpholinyl)-2-butynyl ester (9CI) (CA INDEX NAME)

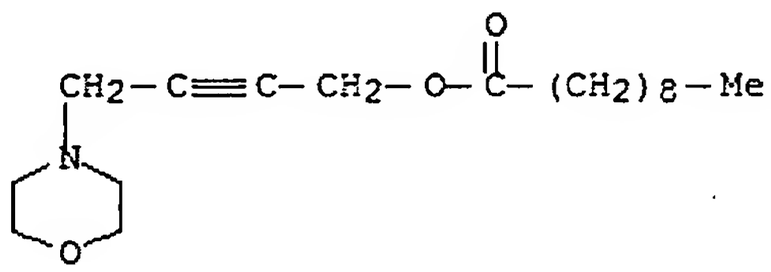


RN 106087-89-2 CAPLUS
CN Hexanoic acid, 4-(4-morpholinyl)-2-butynyl ester (9CI) (CA INDEX NAME)

RN 106087-91-6 CAPLUS
CN Nonanoic acid, 4-(4-morpholinyl)-2-butynyl ester (9CI) (CA INDEX NAME)



RN 106087-92-7 CAPLUS
CN Decanoic acid, 4-(4-morpholinyl)-2-butynyl ester (9CI) (CA INDEX NAME)



Said compounds are the same as applicants when applicants compound of formula I has the following substituents: R = alkyl.

6. Claims 1-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ergashev et al. Khimiko-Farmatsevticheskii Zhurnal (1986), 20(9), 1050-1. The examiner has attached in this Office Action the abstract of said Russian reference in English that shows the prior art compound.

L4 ANSWER 11 OF 38 CAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 1987:27650 CAPLUS Full-text
DOCUMENT NUMBER: 106:27650
TITLE: Synthesis and hypocholesterolemic activity of aminobutynyl linoleates
AUTHOR(S): Ergashev, M. S.; Makhsumov, A. G.; Khadzhiev, A. K.
CORPORATE SOURCE: Med. Inst., Tashkent, USSR
SOURCE: Khimiko-Farmatsevticheskii Zhurnal (1986), 20(9), 1050-1
CODEN: KHFZAN; ISSN: 0023-1134
DOCUMENT TYPE: Journal
LANGUAGE: Russian

AB Me(CH2)4CH:CHCH2CH:CH(CH2)7CO2CH2C.tplbond.CCH2NR2 (I, R = Et or CH2Ph or NR2 = piperidinyl or morpholinyl) were prepared from propargyl linoleate [106059-79-4], CH2O and the appropriate amine. In studies in rabbits with exptl. atherosclerosis and hypercholesterolemia, I (NR2 = morpholino) [106059-82-9] and I (R = CH2Ph) [106059-83-0] were more active as hypocholesterolemics than were the other 2 compds. All were more effective than the hypocholesterolemic Arakhides.

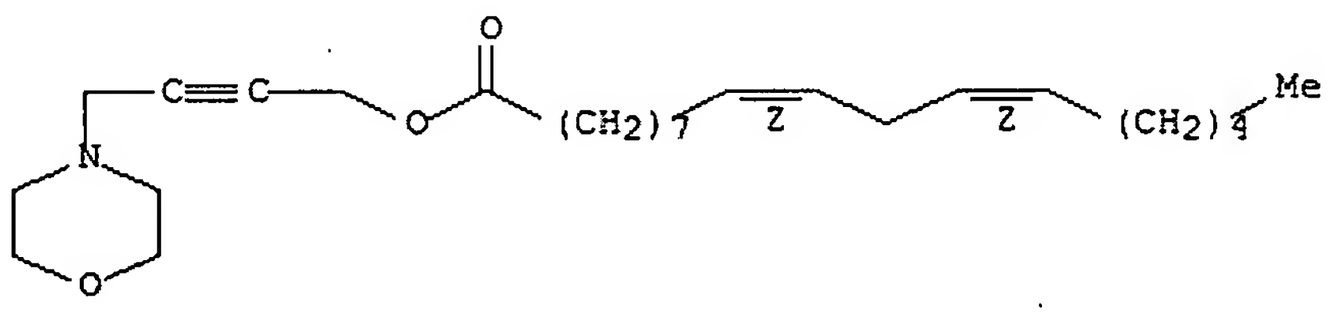
IT 106059-82-9P

RL: SPN (Synthetic preparation); PREP (Preparation)
(preparation and hypocholesterolemic activity of)

RN 106059-82-9 CAPLUS

CN 9,12-Octadecadienoic acid (9Z,12Z)-, 4-(4-morpholinyl)-2-butynyl ester (9CI) (CA INDEX NAME)

Double bond geometry as shown.



This compound is the same as applicants because R = alkyl (unsaturated).

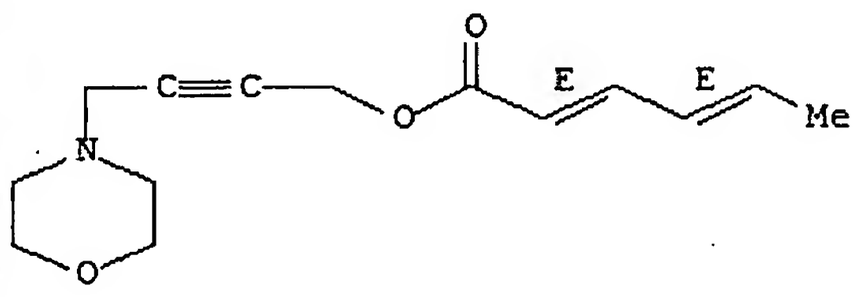
The examiner will provide the reference upon request.

7. Claims 1-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Makhsumov et al. Uzbeskii Khimicheski Zhurnal (1985), (5), 63-65. The examiner has attached in this Office Action the abstract of said Russian reference in English that shows the prior art compound.

L4 ANSWER 12 OF 38 CAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 1987:4504 CAPLUS Full-text
DOCUMENT NUMBER: 106:4504
TITLE: Amino ester acetylene derivatives of sorbic acid
AUTHOR(S): Makhsumov, A. G.; Tadzhibaev, U.; Ergashev, K. S.
CORPORATE SOURCE: Tashk. Gos. Med. Inst., Tashkent, USSR
SOURCE: Uzbekskii Khimicheskii Zhurnal (1985), (5), 63-5
CODEN: UZKZAC; ISSN: 0042-1707
DOCUMENT TYPE: Journal

AB Mannich reaction of propargyl sorbate with R2NH (R = hexyl, octyl, PhCH2; R2N = morpholino, anabasino, cytisino) and paraform in dioxane containing Cu(OAc)2 at 100-105° gave 6 corresponding Me(CH:CH)2CO2CH2C.tplbond.CCH2NR2 in 76.1-92.1% yield.
IT 105566-28-7P
RL: SPN (Synthetic preparation); PREP (Preparation)
(preparation of, by Mannich reaction of propargyl sorbate)
RN 105566-28-7 CAPLUS
CN 2,4-Hexadienoic acid, 4-(4-morpholinyl)-2-butynyl ester, (E,E)- (9CI) (CA INDEX NAME)

Double bond geometry as shown.



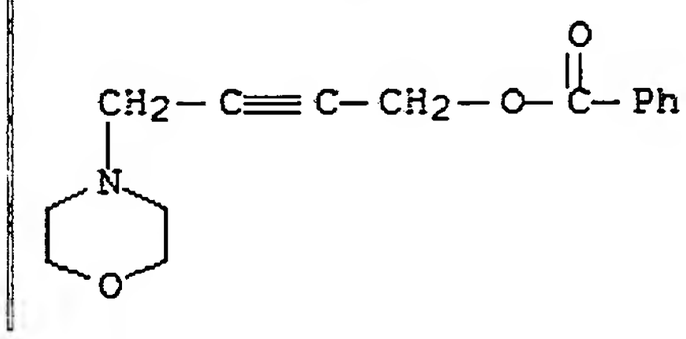
This compound is the same as applicants when applicant's compound of formula I has the following substituent R = alkyl (unsaturated).

The examiner will provide the reference upon request.

8. Claims 1-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kruglikova et al. Izvestiya Vysshikh Uchebnyk Zavedenii, Khimiya i Khimicheskaya Tekhnologiya (1974), 17(12), 1824-7. The examiner has attached in this Office Action the abstract of said Russian reference in English that shows the prior art compound.

L4 ANSWER 15 OF 38 CAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 1975:409070 CAPLUS Full-text
DOCUMENT NUMBER: 83:9070
TITLE: Synthesis of γ-substituted propargyl alcohols, their ethers and esters
AUTHOR(S): Kruglikova, R. I.; Berestevich, B. K.; Babaeva, L. G.; Unkovskii, B. V.
CORPORATE SOURCE: Mosk. Inst. Tonkoi Khim. Tekhnol. im. Lomonosova, Moscow, USSR
SOURCE: Izvestiya Vysshikh Uchebnykh Zavedenii, Khimiya i Khimicheskaya Tekhnologiya (1974), 17(12), 1824-7
CODEN: IVUKAR; ISSN: 0579-2991
DOCUMENT TYPE: Journal
LANGUAGE: Russian

AB RC.tplbond.CCH2OH (R = Me, MeOCH2, CH2:CH, Ph, Me2NCH2, Me2C(OH), 1-hydroxycyclohexyl, PhCH(OH)) were prepared in 38-59% yield. E.g., H2C:CH2C.tplbond.CCH2OH was prepared by treatment of HC.tplbond.CCH:CH2 with EtMgBr, followed by HCHO. R1C.tplbond.CCH2OMe [R1 = H, Me, MeOCH2, Ph, Me2NCH2, MeCO2CH2, ClCH2, BrCH2, MeC(OH)] were prepared in 39-85% yield, usually by methylation of the resp. alcs. RC.tplbond.CCH2O2CC6H4NO2-p (R = H, Me, MeOCH2, Ph, Me2NCH2, Br) and RC.tplbond.CCH2O2CPh (R = H, Me, MeOCH2, CH2:CH, Ph, 1-hydroxycyclohexyl, Me2NCH2, Et2NCH2, piperidinomethyl, morpholinomethyl) were prepared by standard methods.
IT 54757-85-6P 54757-94-7P
RL: SPN (Synthetic preparation); PREP (Preparation)
(preparation of)
RN 54757-85-6 CAPLUS
CN 2-Butyn-1-ol, 4-(4-morpholinyl)-, benzoate (ester) (9CI) (CA INDEX NAME)



This compound is the same as applicants when applicant's compound of formula I has the following substituent R = phenyl. The examiner will provide the reference upon request.

9. Claims 1-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Abdurakihimov et al. Tr. Tashkent. Politekh. Inst. (1970), No. 64, 29-32. The examiner has attached in this Office Action the abstract of said Russian reference in English that shows the prior art compound.

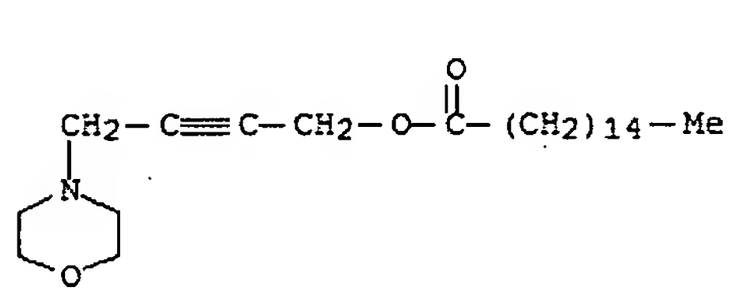
L4 ANSWER 20 OF 38 CAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 1972:526576 CAPLUS Full-text
DOCUMENT NUMBER: 77:126576
ORIGINAL REFERENCE NO.: 77:20853a,20856a
TITLE: Condensation of propargyl palmitate with amines
AUTHOR(S): Abdurakhimov, A.; Makhsumov, A. G.; Safaev, A. S.; Il'khamdzhanov, P.
CORPORATE SOURCE: USSR
SOURCE: Tr. Tashkent. Politekh. Inst. (1970), No. 64, 29-32
From: Ref. Zh., Khim. 1971, Abstr. No. 22Zh230
DOCUMENT TYPE: Journal
LANGUAGE: Russian

AB The maximum yield is obtained in the title reaction if HCHO is used, rather than (HCHO)x, and Cu(OAc)2 is used as catalyst. Thus, 0.015 mole 40% HCHO, 0.01 mole piperidine, 0.01 mole Me(CH2)14CO2CH2C.tplbond.CH, 40 ml dioxane, and 0.15 g Cu(OAc)2 was heated 6 hr at 96-8° to give 83% Me(CH2)14CO2CH2C.tplbond.CCH2R (R = piperidino). Similarly prepared was 82.8% morpholino analog.

IT 38022-01-4P
RL: SPN (Synthetic preparation); PREP (Preparation)
(preparation of)

RN 38022-01-4 CAPLUS

CN Hexadecanoic acid, 4-(4-morpholinyl)-2-butynyl ester (9CI) (CA INDEX NAME)

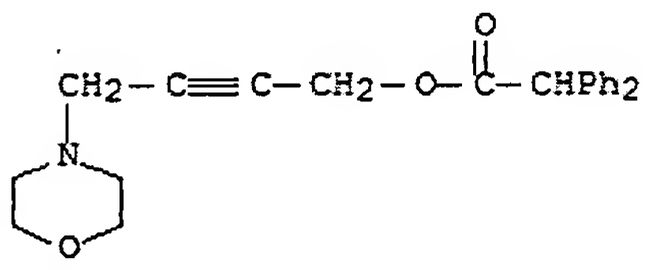


This compound is the same as applicants when applicant's compound of formula I has the following substituent R = phenyl. The examiner will provide the reference upon request.

10. Claims 1-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Dahlbom et al. Acta Chemica Scandinavica (1963), 17, 916-20. The examiner has attached in this Office Action the abstract of said reference that shows the prior art compound.

L4 ANSWER 30 OF 38 CAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 1963:448341 CAPLUS Full-text
DOCUMENT NUMBER: 59:48341
ORIGINAL REFERENCE NO.: 59:8729h,8730a-b
TITLE: Acetylene compounds of potential pharmacological value. I. 4-Amino-2-butynyl esters of diphenylacetic acid, 1-phenylcyclopentane-1-carboxylic acid, and phenothiazine-10-carboxylic acid
AUTHOR(S): Dahlbom, Richard; Mollberg, Rene
CORPORATE SOURCE: Roy. Inst. Pharm., Stockholm
SOURCE: Acta Chemica Scandinavica (1963), 17, 916-20
CODEN: ACHSE7; ISSN: 0904-213X
DOCUMENT TYPE: Journal
LANGUAGE: English
AB Esters of diphenylacetic acid (I), 1-phenylcyclopentane-1-carboxylic acid (II), and phenothiazine-10-carboxylic acid (III) with RCH2C.tplbond.CCH2OH (IV) have been prepared, where R = NMe2 (V), NEt2 (VI), pyrrolidino (VII), piperidino (VIII), and morpholino (IX). IV was obtained from ClCH2C.tplbond.CCH2OH and the appropriate amine by the method of Biel (B., et al., CA 52, 6335g). Reported were IV (R, % yield, b.p./mm., and n22D given): VII, 85, 112-13°/0.9, 1.5092; VIII, 71, 101-2°/0.4, 1.5043. A solution of 0.055 mole acid chloride, 0.05 mole IV, and 0.06 mole Et3N in 50 ml. C6H6 was refluxed 3-20 hrs., then cooled, filtered, and concentrated in vacuo. The residue was dissolved in 50 ml. Et2O, treated with HCl and the precipitate recrystd. from Et2O-EtOH. Quaternary salts of III esters were also prepared The following RCH2C.tplbond.CCH2R1R2X were obtained (RH, R1, R2X, % yield, and m.p. given): III, V, HCl, 48, 185-6° (decomposition); III, V, EtBr, 83, 158-9° (decomposition); III, VI, HCl, 61, 181-2° (decomposition); III, VI, MeBr, 91, 141-2° (decomposition); III, VII, HCl, 69, 155.5-6.5° (decomposition); III, VII, MeBr, 89, 163-4° (decomposition); III, VIII, HCl, 72, 176-7° (decomposition); III, VIII, MeBr, 98, 170-1° (decomposition); III, IX, HCl, 64, 188-9° (decomposition); II, V, HCl, 86, 144-6°; II, VI, HCl, 57, 92.5- 4°; II, VIII, HCl, 65, 124-6°; II, IX, HCl, 71, 167-9°; I, VI, HCl, 79, 128-30°; I, VII, HCl, 83, 142-4°; I, VIII, HCl, 78, 158-60°; I, IX, HCl, 80, 160-1.5°.
IT 97417-91-9 98075-12-8 98222-92-5
98249-62-8
(Derived from data in the 7th Collective Formula Index (1962-1966))

RN 95130-43-1 CAPLUS
CN Acetic acid, diphenyl-, 4-morpholino-2-butynyl ester, hydrochloride (7CI) (CA INDEX NAME)



● HCl

This compound is the same as applicants when applicant's compound of formula I has the following substituent R = methyl substituted by phenyl. The examiner will provide the reference upon request.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claim 10, it is recited a method of treating a cell proliferative disorder including neoplasia (claim 11), but the specification is not enabled for such a scope.

A number of factors are relevant to whether undue experimentation would be required to practice the claimed invention, including "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

(1). Breadth of Claims: Claims 10-12 are directed to a method of treating a cell proliferative disorder including neoplasia selected from leukemias, lymphomas, etc. that comprises administering to a patient benefiting from such treatment at least one compound of claim 1 or a pharmaceutically acceptable salt.

a. Scope of use - The scope of use that applicants intend to claim is very broad. To this day, it is impossible to treat a cell proliferative disorder with a single pharmaceutical drug. A proliferative disorder is anything that causes any abnormal tissue growth. That can be growth by cellular proliferation more rapidly than normal, or continued growth after the stimulus that initiated the new growth has ceased, or lack (partial or complete) of structural organization and/or coordination with surrounding tissue. It can be benign or malignant. Thus, such a term covers not only all cancers, but also covers precancerous conditions such as lumps, lesions, and polyps. In addition, it embraces

various non-cancerous proliferative disorders such as certain types of restenosis, vascular smooth muscle proliferation associated with atherosclerosis, glomerular nephritis, clonal proliferative disorders including the various Myelodysplastic Syndromes such as Refractory anemias, certain types of abnormal wound healings, different types of abnormal angiogenisis, pulmonary fibrosis, macular degeneration, myeloproliferative disorders such as primary polycythemia and myleofibrosis, and rheumatoid arthritis. There is no such thing that an agent which is effective against such disorders generally, since they are so diverse, nor is there any reason to think that such an agent could be made to work.

b. Scope of Compounds - The scope of the compounds is also broad. It is apparent that thousands of combinations of compounds can be created from the definitions, owing especially to broad scope of R and the substituents on the morpholine.

(2). Direction of Guidance: The amount of direction or guidance is minimal. There is no guidance in the specification for the treatment of cell proliferative disorder in general or neoplasia.

(3). State of Prior Art: There is no evidence of record that compounds structurally similar to these morpholinyl compounds of formula I are in use for the treatment of a cell proliferative disorder in general.

(4). Working Examples: The working examples at pages 71-74 discloses % inhibition growth data for L2, L4, L6, L9, L12-13 and L15-16, but there is no way to convert this data into specific useful knowledge, especially in view of the difficult nature of some of these disorders.

(5). Nature of the Invention and Predictability: The invention is directed to a method of treating a cell proliferative disorder. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Cell proliferative disorder are especially unpredictable due to their complex nature.

(6). The Quantity of Experimentation Necessary: Immense, because so many cell proliferative disorders are covered; see part (1).

(7). The Relative Skill of Those in the Art: The relative skill is extremely very low. To this day, there is no magic bullet that can treat all cell proliferative disorders in general.

When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, *In re Ferens*, 163 USPQ 609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006.

It is recommended that applicants delete claims 10-12 to overcome this rejection.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claim 1 and claims dependent are rejected because the term "their bis-(2-butynyl)diesters" is not clear. What is covered and what is not? What is the definition of R for said diesters? Can R be a bond for said diesters?

b. In claim 1 (page 5, line 6), the phrase "can be replaced by **0**, S or N" should read "can be replaced by **O**, S or N". Note that zero (0) should be changed to letter O.

c. In claims 9 and 14, the phrase "for use" is a mental step. Do applicants intend a composition claim or a method of use claim? If they intend a method of use claim, then the claim should be written as a method of use claim. It is recommended that applicants delete this phrase from claims 9 and 14.

d. In claim 10, the nomenclature of the compound is not clear. The compound M4-(N-substituted amino)-2-butynyl-1-ester starts with M4, but it is unclear what M4 stands for. Is M a typographical error?

e. In claim 10, the phrase "in a cell proliferative disorder treating effective amount" is not clear. The phrase appears to be garbled or incomplete.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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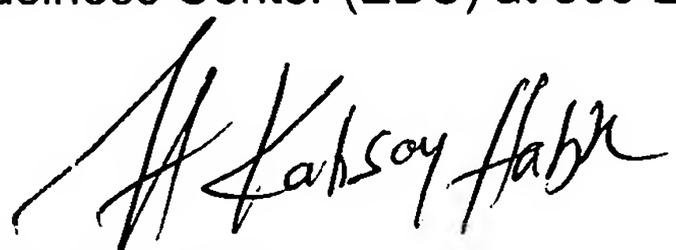

Kahsay Habte
Primary Examiner
Art Unit 1624

KH
October 30, 2007